

REMARKS

Claims 1-11 are pending and stand rejected. Reconsideration is respectfully requested in view of the following remarks.

Amendments to the Claims

Applicant amends claim 1 to recite that the biodegradable, composite interference screw degrades in the body. Support for the amendment can be found throughout the specification, particularly at paragraph 0033. No new matter is added.

Claim Rejections Pursuant to 35 U.S.C. §103

The Examiner rejects claims 1-11 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,632,748 of Beck, Jr. et al. ("Beck"). Applicant respectfully disagrees with the Examiners rejection.

Claim 1 recites, in pertinent part, providing a biodegradable, composite interference screw including a copolymer of poly (lactic acid) and poly(glycolic acid), and a bioceramic, inserting the biodegradable screw into a femoral bone tunnel, and rotating the interference screw such that the screw is substantially contained within the femoral bone tunnel.

The Examiner alleges that Beck discloses providing a graft in bone tunnels formed in the femur and tibia, that the grafts are secured in the tunnels by an interference screw that may be formed of biodegradable materials, and that the tunnels are tapped by the self tapping threads of the device. The Examiner admits that Beck does not disclose that the biodegradable material comprises a copolymer of polylactic or polyglycolic acid and a bioceramic such as TCP or other calcium phosphates, hydroxyapatite, calcium sulfates, calcium oxides, calcium carbonates, and magnesium phosphates. However, the Examiner argues that it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the device of a biodegradable material comprising a copolymer of polylactic or polyglycolic acid and a bioceramic such as TCP or other calcium phosphates, hydroxyapatite, calcium sulfates, calcium oxides, calcium carbonates, and magnesium phosphates because it would have been within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

At the outset, claim 1 recites a combination of materials, a “copolymer,” not simply a selection of a known material. Simply stating that the combination of materials would have been selected on the basis of their individual suitability for the intended use is not enough when the prior art gives no indication that the *combination* of materials would perform in the claimed method when combined. Accordingly, the Examiner’s assertion that it was within the general skill of a worker in the art to select the materials, without any evidence that the combination would perform in the claimed method, is not enough to establish a *prima facie* case of obviousness.

Regardless, Applicant submits the attached §1.132 Declaration of Lisa Donnelly (the “Declaration”) in support of the patentability of the claimed invention. As the Declaration indicates, the claimed materials would not have been an obvious design choice because, until Applicant’s invention, these materials were not well suited for use with bone anchors. Applicant’s invention addresses a problem that has been recognized for a long time. *See* paragraphs 7 and 8 of the Declaration. Biodegradable interference screws that could be used in the claimed method were not available until Applicant’s invention thereof. *See* paragraph 6 of the Declaration. Recognizing this long felt but unresolved need, Applicant made substantial developments to arrive at the current invention. *See* paragraph 8 of the Declaration. Accordingly, it would not have been obvious to use the claimed materials with the bone screw of Beck.

The Examiner also argues that the particulars of the material to be used do not affect the method in a manipulative sense. At the outset, Applicant disagrees as claim 1 specifically recites *providing* a bone screw formed from a biodegradable polymer comprising a copolymer of poly lactic or polyglycolic acid and a bioceramic. Regardless, Applicant amends claim 1 to recite that the biodegradable interference screw degrades in the body. The biodegradable copolymer recited in claim 1 therefore affects the method in a manipulative sense, and thus the structural limitations must be given patentable weight.

In view of the foregoing, independent claim 1, as well as claims 2-11 which depend therefrom, distinguish over Beck and represent allowable subject matter.


Conclusion

Applicant submits that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite the prosecution of this application.

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Respectfully submitted,



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